

Express Mail EL300242708US

1 DIGITAL PRESCRIPTION CARRIER AND MONITOR SYSTEM

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Background of the Invention

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5 Other than surgery, non-invasive manipulation, and
6 nutrition, the major means of treating diseases and medical
7 conditions is by the use of prescribed and over-the-counter
8 drugs. Drugs which can be harmful if misused or abused are
9 usually required by regulation to be prescribed by a
10 licensed physician and dispensed by a licensed pharmacist.

11 A prescription is conventionally a written order or
12 "script" by a physician identifying the medication to be
13 dispensed, the dosage, and the time interval at which the
14 dosage is to be taken, or applied in the case of a topical
15 drug. The identity of the drug may include the brand name
16 or its pharmaceutical equivalent. Dosage may include the
17 concentration or the weight of the tablet or capsule
18 containing the active ingredient and may include special
19 instructions, such as before or after meals, before bedtime,
20 or the like. A total number of dosage units is sometimes
21 factored into the dosage for a given medication. In
22 general, prescriptions are intended to achieve and maintain
23 a desired concentration of a drug within a patient for a
24 selected length of time to treat a medical condition.

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1 One problem with the conventional manner of
2 prescriptions is that they are handwritten on a slip of
3 paper. Although errors in filling prescriptions because of
4 legibility problems are rare, they can occur with
5 potentially serious consequences. A conscientious
6 pharmacist will call the prescribing physician if there are
7 any doubts about the prescription script. Another potential
8 problem is that prescriptions can be counterfeited by use of
9 a physician's prescription forms. This usually occurs only
10 with drugs having an abuse or addiction potential. Another
11 problem is that the benefit of a prescribed drug can be
12 diminished if the patient does not follow the prescribed
13 schedule in taking it.

14 Electronic prescription reminder devices which are
15 programmed with the prescription schedule of one or more
16 drugs are known. Such a device sounds an alarm when it is
17 time to take a medication according to the schedule. Also
18 known are devices which record compliance by the patient in
19 taking a prescription. However, the problems in clearly
20 conveying the prescription information to the pharmacist and
21 prevention of counterfeiting or tampering with prescriptions
22 are not addressed by these devices.

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1 Summary of the Invention

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3 The present invention provides a method and a

4 prescription carrier apparatus for storing prescription data

5 by a physician and for retrieval by a pharmacist. The

6 carrier data cannot be accessed by the patient; however, the

7 carrier also functions as a prescription reminder for the

8 patient and as a prescription compliance recorder.

9 The prescription carrier is a device roughly the size

10 of a paging receiver or pager and has a dot matrix liquid

11 crystal display (LCD), an infrared (IR) communications

12 interface, pushbutton keys, a sound alert, and a vibration

13 alert. Internally, the carrier includes a microprocessor,

14 non-volatile memory, a real-time clock/calendar, and

15 interface circuitry to the LCD display, the IR

16 transmit/receive devices, the keys, and the alert devices.

17 Data access to the prescription carrier is made by way

18 of the IR interface which includes IR receiver and

19 transmitter devices. Such IR interfaces are provided on

20 some laptop computers for communication functions, such as

21 conveying data to be printed to a printer without electrical

22 connection of the laptop to the printer. The IR interface

23 provides for communication with a physician's computer or a

1 pharmacist's computer, both of which are provided with
2 appropriate software to respectively upload or download
3 prescription and/or compliance data. The prescription data
4 may be in the form of a data record with data fields which
5 can be parsed by software within the prescription carrier to
6 retrieve the name of the medication along with dosage
7 factors and dosage scheduling. The processor within the
8 carrier uses the dosage scheduling data to set up a
9 prescription reminder schedule for each medication in
10 cooperation with the real time clock/calendar and the alert
11 devices. By this means, the carrier alerts the patient each
12 time a dose of the prescription medication is due.

13 The prescription carrier includes a "delay" switch and
14 a "take" switch. The delay switch functions similar to a
15 "snooze" button on a conventional alarm clock. It initiates
16 a delay clock function to alert again at the end of a delay
17 period, for example, of ten or fifteen minutes. Some
18 prescriptions may not allow delays in taking a dose. The
19 take switch is operated when the patient takes a medication
20 upon being alerted to do so and also deactivates the alert
21 device. While operation of the delay switch is not
22 generally recorded, operation of the take switch is recorded
23 as a "compliance" with the prescription. Each compliance

1 record may include the identity of the medication and the
2 time and date that the take switch was operated. The
3 compliance data can be downloaded by the prescribing
4 physician to compare treatment progress with prescription
5 compliance or to simply determine if the patient has or has
6 not been taking the medication as prescribed.

7 Because allowing the patient access to data within the
8 prescription carrier could result in obvious problems, such
9 access is restricted to the prescribing physician and the
10 pharmacist, or their employees. Access can be restricted by
11 the use of simple passwords. However, the data within the
12 prescription carrier of the present invention is preferably
13 encrypted using one or more encryption keys or digital
14 signatures which are available only to the physician and the
15 pharmacist, but not to the patient. The sciences of
16 effective techniques for encryption of digital data and
17 encryption keys for decrypting are well developed.
18 Background information on such encryption and digital
19 signature techniques can be obtained from U. S. Patent Nos.
20 4,200,770 and 5,537,475, which are incorporated herein by
21 reference. If the present invention, digital signatures
22 incorporating license numbers issued by the U. S. Drug
23 Enforcement Agency (DEA) are preferred.

1 Objects and Advantages of the Invention

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3 The principal objects of the present invention are: to

4 provide an improved method and apparatus for conveying a

5 prescription medication from a physician to a patient; to

6 provide such a system including a portable prescription

7 carrier apparatus in which data representing the

8 prescription is uploaded by a physician and downloaded by a

9 pharmacist to fill the prescription; to provide such a

10 prescription carrier apparatus including circuitry and logic

11 which is programmable with prescription data including a

12 prescription schedule for alerting a patient when a dose of

13 a medication is due; to provide such a carrier apparatus

14 which is operable to record compliance of the patient with

15 the prescription for subsequent downloading and analysis by

16 the prescribing physician; to provide such a carrier

17 apparatus which is similar in size and shape to a pager

18 receiver and which includes both sonic and vibratory alert

19 devices; to provide such a carrier apparatus in which

20 prescription data therein is encrypted and which cannot be

21 decrypted by the patient to thereby prevent falsification or

22 counterfeiting of the prescription data therein; and to

23 provide such a digital prescription carrier and monitor

1 system which is economical to manufacture, which is precise
2 and effective in use, and which is particularly well adapted
3 for its intended purpose.

4 Other objects and advantages of this invention will
5 become apparent from the following description taken in
6 conjunction with the accompanying drawings wherein are set
7 forth, by way of illustration and example, certain
8 embodiments of this invention.

9 The drawings constitute a part of this specification
10 and include exemplary embodiments of the present invention
11 and illustrate various objects and features thereof.

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13 Brief Description of the Drawings

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15 Fig. 1 is a front elevational view of a digital
16 prescription carrier and monitor system which embodies the
17 present invention.

18 Fig. 2 is a block diagram illustrating the principal
19 circuit components of the digital prescription carrier and
20 monitor system.

21 Fig. 3 is a flow diagram illustrating the principal
22 software components of the system.

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1 Detailed Description of the Invention

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3 As required, detailed embodiments of the present
4 invention are disclosed herein; however, it is to be
5 understood that the disclosed embodiments are merely
6 exemplary of the invention, which may be embodied in various
7 forms. Therefore, specific structural and functional
8 details disclosed herein are not to be interpreted as
9 limiting, but merely as a basis for the claims and as a
10 representative basis for teaching one skilled in the art to
11 variously employ the present invention in virtually any
12 appropriately detailed structure.

13 Referring to the drawings in more detail:

14 The reference numeral 1 generally designates a digital
15 prescription carrier and monitor device which embodies the
16 present invention. In general, the carrier 1 is adapted to
17 have prescription data uploaded thereinto from a physician's
18 computer for transportation to a pharmacy at which the
19 prescription data is downloaded into a pharmacist's computer
20 and the prescription filled. The carrier 1 is also adapted
21 to provide alerts at times when the prescribed medication is
22 to be taken in accordance with the prescription and to
23 record compliance by the patient with the prescription.

1 The carrier 1 includes an outer housing 2 sized similar
2 to a pager and may include a resilient belt clip (not shown)
3 for wearing the carrier 1 on the belt of a patient or user.
4 The housing 2 includes a dot-matrix liquid crystal display
5 3, operation buttons 4, an alert device selection switch 5,
6 a sonic output device 6, and infrared interface link windows
7 7 and 8. The illustrated carrier 1 includes buttons for
8 scrolling up 14, scrolling down 15, delay 16, take 17, and
9 backlight toggle or light 18. The housing 2 also has a
10 battery (not shown) which powers circuitry 20 (Fig. 2)
11 therein through a low battery detector power supply 21.

12 The circuitry 20 includes a central processing unit or
13 CPU 24 which may be a microprocessor or microcontroller.
14 The processor 24 includes, among other on-chip components,
15 non-volatile RAM memory 26 and a real-time clock/calendar
16 27. Alternative to, or in addition to, the non-volatile RAM
17 26, the CPU 24 may include or be interfaced with read-only
18 memory (ROM) and/or conventional memory or RAM (neither
19 shown). Software 30 (Fig. 3) which operates within the
20 carrier 1 is stored in the non-volatile RAM 26.

21 The operation buttons or switches 4 are interfaced to
22 the CPU 24, as is the LCD display 3. LCD driver circuitry
23 32 interfaces the display circuitry 3 to the CPU 24.

1 Preferably, the display 3 is a dot-matrix type which
2 provides greater flexibility of characters which can be
3 displayed thereon than, for example, 7-segment type
4 displays. The illustrated display 3 may, for example, be a
5 commonly available 16 character by 2 line display. The
6 illustrated carrier 1 includes the scroll buttons 14 and 15,
7 the delay switch 16, the take switch 17, the backlight
8 switch 18, and the alert select switch 5. However, it is
9 foreseen that other user-selected functions may be desirable
10 in the carrier 1, such that the carrier 1 is not intended to
11 be limited only to the switches shown. The backlight switch
12 18 toggles one or more light emitting diodes or LED's (not
13 shown) which illuminate the display 3 to facilitate reading
14 the display in darkness. Although the display 3 is
15 preferably formed using liquid crystal display technology
16 because of its low power consumption and ready availability,
17 other display technologies could alternatively be employed.

18 The carrier 1 is provided with the sonic alert device 6
19 to remind the user that it is time for a dose of a
20 medication, the schedule for which is being tracked by the
21 carrier 1. The sonic alert device 6 may be a small
22 loudspeaker or other audio transducer capable of generating
23 an acoustic signal. The device 6 is powered by sonic drive

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1 circuitry 36 and interfaced to the CPU 24 thereby. The
2 sonic drive circuitry 36 may simply be a power amplifier or
3 may incorporate other elements. The carrier 1 is also
4 preferably provided with a vibrating alert device 38 in
5 cooperation with vibrator drive circuitry 40. Such
6 vibrating alert devices are common in paging receivers and
7 generate a tactile vibration when activated. The alert mode
8 selection switch 5 enables the user to select either the
9 sonic alert 6, the vibrating alert 38, or both. Although
10 not illustrated, it is also foreseen that the carrier 1
11 could be provided with a flashing lamp as an alternative
12 alert device for hearing impaired persons, although such
13 persons would still benefit from the vibrating alert 38.

14 The carrier 1 includes a communication port 42 for
15 interfacing the carrier 1 to an external computer or PC
16 system 44. Such a communication port 42 could be a
17 conventional RS-232 serial port or a more recent
18 communication interface such as a universal serial bus (USB)
19 interface, a "Firewire" (trademark of Apple Computer, Inc.)
20 interface, or the like. In the illustrated carrier 1, the
21 communication port 42 is an infrared (IR) data link 46
22 including a transmitter (TX) channel 48 and a receiver (RX)
23 channel 50. Such IR links 46 are provided on some laptop

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1 computers, as well as on some peripheral devices, such as
2 printers, so that a document can be printed from the laptop
3 computer by the printer without a conductive connection. In
4 the carrier 1, the IR port 46 is used to upload a
5 prescription data into the carrier 1 and to download such
6 data from the carrier 1.

7 Fig. 3 illustrates the principal functions of the
8 software 30 which is executed by the CPU 24 of the carrier
9 1. In general, the carrier 1 is able to track the schedules
10 for a plurality of medications, the number of which is
11 limited by the size of the RAM 26, in cooperation with the
12 real-time clock/calendar 27. When a dose of a medication is
13 due, one or both of the alert devices 6 and/or 38 is
14 activated. The user of the carrier 1 can review the
15 upcoming medication schedule on the display 3 using the
16 scroll keys 14 and 15. The prescription data is entered
17 into the carrier 1 from an external computer 44 and accessed
18 to fill the prescriptions by way of the IR data link 46.
19 The external computer 44 executes special software (not
20 detailed herein) to access the carrier 1.

21 Referring particularly to Fig. 3, from the start
22 function 52, when a new battery (not shown) is installed in
23 the carrier 1, a main loop 53 is entered. The main loop 53

1 operated, at 61, the alert device 6/38 is deactivated,
2 operation of the take switch 17 is recorded, at 62, as a
3 "compliance" with the prescription, and the time of
4 compliance is recorded by the CPU 24 in the RAM 26. After
5 recording compliance at 62, the CPU 24 returns to the mode
6 test 54.

7 When the IR data link 46 is activated at 57, a
8 communication test is run at 64. If a communication link
9 has not been established with an external computer 44 by the
10 end of the wait interval, the IR data link 46 is deactivated
11 and control is returned to the mode test 54. If
12 communications have been established at 64, a security test
13 65 is entered, requiring the entry of a valid encryption key
14 or a password. If the entered encryption key or password is
15 not correct, communication between the carrier 1 and the
16 external computer 44 is disabled at 66 and control is passed
17 to the mode test 54.

18 If the encryption key or password is valid, a
19 communication mode test 67 is conducted to determine if a
20 pharmacy mode 68 or a doctor mode 69 is to be entered. In
21 the pharmacy mode 68, the pharmacist is allowed to access
22 all the current prescriptions, to decrement refill counts of
23 certain prescriptions, and to view patient information which

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1 is stored in the carrier 1. The doctor mode 69 includes all
2 pharmacy mode privileges and additionally allows entry and
3 deletion of prescriptions, entry or update of patient
4 information, and access to prescription compliance data.

5 Most states still require the presentation of a
6 prescription form signed by a physician for certain
7 medications, especially those with a high potential for
8 abuse. Prescriptions for other drugs may be "called in".
9 The carrier 1 has utility as a sole prescription carrier or
10 as a digital version of a conventional signed prescription
11 form. The digital prescription data stored in the carrier 1
12 can be uploaded into the pharmacy computer system for
13 inventory control purposes, as well as to reduce data entry
14 errors and for cross-checking purposes. Thus, the carrier 1
15 of the present invention complements the functions of
16 current paper based methods of filling prescriptions rather
17 than simply replacing or duplicating such functions. The
18 carrier 1 also has a reminder function and a compliance
19 recording functions. The data link 46 gives the carrier 1
20 the capability of being accessed remotely, for example over
21 the internet, for the entry or modification of prescriptions
22 by the physician or review of the prescriptions or
23 compliance data by the physician or pharmacist.

1 It is to be understood that while certain forms of the
2 present invention have been illustrated and described
3 herein, it is not to be limited to the specific forms or
4 arrangement of parts described and shown.
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